

## REMARKS

### 1. Preliminary Remarks

#### a. Status of the Claims

Claims 21-40 are pending this application. Claims 22, 26, 29-34, and 39-40 are hereby canceled without prejudice to pursuing the canceled subject matter in a continuing application. Claims 21, 25, and 37 are amended. Upon entry of these amendments, claims 21, 23-35, 27, 28, and 35-38 are pending and at issue. Applicant respectfully requests entry of the foregoing amendments and following remarks.

#### b. Amendments to the Claims

Claim 21 is amended in part to recite an isolated nucleic acid consisting of X nucleotides wherein X = 18 to 120. This amendment is merely a rewording of the limitation that the nucleic acid consists of 18 to 120 nucleotides. Claim 21 is also amended to recite that the nucleic acid comprises at least Y consecutive nucleotides of SEQ ID NOs: 1916 or 1917, wherein  $Y \geq 18$ , support for which may be found at Table 1, lines 13408-13412 and 13415-13419, and paragraphs 26978 and 26992 of the application as originally filed. The limitation that that the nucleic acid is at least Y consecutive nucleotides wherein  $Y \geq 18$  is merely a rewording of the limitation that the nucleic acid comprises at least 18 consecutive nucleotides.

Claim 21 is also amended to recite that the nucleic acid comprises a sequence at least 58.7% identical to (a) or (b), support for which can be found at Table 1, lines 13408-13412 and paragraph 42972 of the application as originally filed. As described in paragraph 42972, VGR3152 encodes VGAM1930 (represented by SEQ ID NO: 1916). SEQ ID NO: 1916 forms a hairpin, as shown at Table 1. SEQ ID NO: 1916 is 58 nucleotides in length. Within the predicted hairpin formed by SEQ ID NO: 1916, 34 complementary nucleotides are paired. The ratio 34/58 expressed as a percent, rounded up to the nearest tenth, is equivalent to 58.7%.

Claim 23 is amended to reword the limitation of the at least 18 nucleotides to the Y nucleotides, which now has antecedent basis in limitation (a) of claim 21 (“... wherein  $Y \geq 18$ ”). Claim 23 is also amended to correct a typographical error. These specific amendments do not change the scope of the claim.

Claim 24 is amended to recite that the nucleic acid has a length wherein  $X = 18$  to  $24$ , which has antecedent basis in claim 21 (“wherein  $X = 18$  to  $120$ ”). This amendment is a rewording of the limitation of claim 24 that the nucleic acid consists of  $18$  to  $24$  nucleotides.

Claim 25 is amended to recite that the nucleic acid has length wherein  $X = Y$ , which is merely a rewording of the limitation that the nucleic acid of claim 25 consists of a sequence recited in claim 21. This specific amendment does not change the scope of the claim.

Claim 27 is amended to reword the limitation of the at least  $18$  nucleotides to “the  $Y$  nucleotides,” which has antecedent basis as described above for amended claim 23. This specific amendment does not change the scope of the claim.

Claim 28 is amended to recite that the nucleic acid has a length wherein  $X = 18$  to  $24$  nucleotides, which is a rewording of the claim as described for amended claim 24. This specific amendment does not change the scope of the claim.

Claim 37 is amended to correct a typographical error in the phrase “A probe comprising insert” to recite “A probe comprising an insert.”

#### **c. Amendments to the Specification**

Paragraphs 0003, 0004, 0006, 0066, 0070 and 0071 of the specification have been amended to replace the incorrectly spelled word “complimentary” with the word “complementary.”

Paragraph 0044 has been amended to include text that includes a description of Fig. 6C, support for which can be found at Figure 6C as originally filed.

#### **d. Priority of Claimed Sequences**

On page 2 of the Office Action, the Examiner alleges that no support could be found in priority U.S. Provisional Patent Application No. 60/457,788 (the “Priority Application”) for SEQ ID NOs: 46759, 1916, 1917, 4641, or 4642. The Examiner has therefore assigned a priority date of August 29, 2003, which is the filing date of the instant application, to these sequences.

Applicant submits that SEQ ID NOs: 46759, 1916 (VGAM1930), 1917 (VGAM1931), 4641, and 4641 are disclosed in the Priority Application. Paragraphs 566-571 of the file entitled “cluster 003100-003199.txt” of the Priority Application<sup>1</sup> disclose that VGAM1930 and VGAM1931 are encoded by GR413, which is the same as VGR3152 of the instant application.

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<sup>1</sup> The file entitled “cluster 003100-003199.txt” is located in the folder entitled “Pal description” on the CD entitled “Description & Figs 17-2739 2741-3297” that was filed with the Priority Application

Using the reasoning above in the written description support provided for amended claim 21 (See Section 1b, paragraph 1), paragraphs 566-571 of the Priority Application likewise establish that the Priority Application provided written description support for SEQ ID NO: 46759.

SEQ ID Nos: 1916, 1917, 4641, and 4642 in the Sequence Listings of the Priority Application and the instant application are identical. In addition, SEQ ID NOS: 1916 and 4641 of the instant application are identical to SEQ ID NOS: 1916 and 4641 as shown in Figure 1930B of the Priority Application<sup>2</sup>.

Similarly, SEQ ID NOS: 1917 and 4642 of the instant application are identical to SEQ ID NOS: 1917 and 4642 as shown in Figure 1931B of the Priority Application<sup>3</sup>. Therefore, Applicant submits that the Priority Application supports SEQ ID Nos: 1916, 1917, 4641, and 4642.

In view of the foregoing remarks, Applicant respectfully requests that SEQ ID NOS: 46759, 1916, 1917, 4641, and 4642 be assigned a priority date of March 27, 2003, which is the filing date of the Priority Application.

#### **e. Information Disclosure Statement**

On pages 2 and 3 of the Office Action, the Examiner alleges that the information disclosure statement filed October 3, 2006 fails to comply with 37 C.F.R. § 1.98(a)(3). Specifically, the Examiner alleges that reference B5 is not in the English language, and therefore can not consider reference B5 for examination purposes. Applicant respectfully submits that the Examiner is in error because reference B5 is in English, and is unsure of the Examiner's reasons for the objection. Nonetheless, in order to expedite prosecution, Applicant hereby resubmits an Information Disclosure Statement pursuant to 37 C.F.R. §§ 1.56, 1.97 and 1.98 along with a copy of reference B5.

#### **f. Objections to the Specification**

On page 3 of the Office Action, the Examiner objects to the specification for the alleged misspelling of the word "complementary." The Examiner also requires correction of the brief description of the drawings, which allegedly contain no description of Figure 6C.

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<sup>2</sup> Figure 1930B is the file entitled "fig-001930\_0001.tif," which is in the folder entitled "Figs17-2739, 2741-3297" on the CD entitled "Description & Figs 17-2739 2741-3297" that was filed with the Priority Application

<sup>3</sup> Figure 1931B is the file entitled "fig-001931\_0001.tif," which is in the same folder as Figure 1930B of the Priority Application.

Amended paragraphs 0003, 0004, 0006, 0066, 0070, and 0071 now disclose the correct spelling of the word “complementary.” The specification is further amended at paragraph 0044 to add a brief description of Figure 6C. Applicant respectfully submits that the objection to the word “complementary” was a typographical error and was not amended for substantive reasons, and the brief description of Figure 6C does not add new matter.

In view of the amendments to the specification described hereinabove, Applicant respectfully requests that the objections to the specification be reconsidered and withdrawn.

**g. Provisional Rejection, Obviousness-Type Double Patenting**

On page 4 of the Office Action, the Examiner provisionally rejects claims 21-30 and 35-40 under nonstatutory obviousness-type double patenting over claims 1-3, 10, 13, and 14 of copending Application No. 10/535,164.

On page 5 of the Office Action, the Examiner provisionally rejects claims 21-30 and 35-40 under nonstatutory obviousness-type double patenting over claims 1-3, 8, 11, and 12 of copending Application No. 10/605,838.

On pages 5 and 6 of the Office Action, the Examiner further notes that the following copending Application Nos. allegedly contain claims in which an obviousness-type double patenting rejection might be applied or contain claims for which it cannot be determined if the claimed sequences are the same. The Examiner specifically alleges that U.S. Patent Application Nos. 11/511,035; 11/384,049; 11/709,691; 10/708,953; 10/536,560; 10/605,840; 10/709,572; 10/709,739; 11/130,649; 10/604,985; 10/605,923; 10/707,003; 10/707,147; 10/707,975; 10/708,204; 10/708,951; 10/708,952; 11/418,870; 10/604,726; 10/604,926; 10/604,943; 10/604,945 may be used in the future for obviousness-type double patenting.

In view of the amendments and remarks made herein, Applicant believes that the only outstanding rejections are obviousness-type double patenting rejections, which will allow the Examiner to withdraw the provisional rejections and convert each to a double patenting rejection in the co-pending cases. In view of the instant application being filed earlier than the cited applications, Applicant respectfully requests that the obviousness-type double patenting rejection be withdrawn pursuant to MPEP 804.I.B.1.

**h. Objections to the Claims**

On pages 6 and 7 of the Office Action, the Examiner objects to claims 31-34 under 37 C.F.R. § 1.75(c) as allegedly being of improper dependent form for failing to limit the subject

matter of a previous claim. In the interest of expediting prosecution, claims 31-34 are canceled without prejudice to pursuing the canceled subject matter in a continuing application, rendering the objection moot.

## **2. Patentability Remarks**

### **a. Rejection Pursuant to 35 U.S.C. § 112, Second Paragraph**

#### ***Claims 39-40***

On pages 8 and 9 of the Office Action, the Examiner rejects claims 39 and 40 under 35 U.S.C. § 112, second paragraph, for allegedly being indefinite. Solely to expedite prosecution, and without prejudice to seeking broader claims in a continuing prosecution, claims 39 and 40 are hereby canceled. In view of the foregoing amendment, Applicant respectfully submits that the rejection of claims 39 and 40 under 35 U.S.C. § 112, second paragraph, is moot and should be withdrawn.

#### ***Claims 25-28, 30, 36, 38, and 40***

On page 9 of the Office Action, the Examiner rejects claims 25-28, 30, 36, 38, and 40 under 35 U.S.C. § 112, second paragraph. Specifically, the Examiner alleges that claim 25, which depends from claim 21, recites a nucleic acid consisting of SEQ ID NO: 46759, which is 761 nucleotides in length, while claim 21 recites a nucleic acid consisting of only 18-120 nucleotides in length. The Examiner asserts that because the maximum length of the claimed nucleic acid is 120 nucleotides, it is unknown how the nucleic acid of claim 25 could consist of the entirety of SEQ ID NO: 46759. The Examiner likewise rejects claim 28 because this claim allegedly recites a sequence with a maximum length of only 24 nucleotides even though this claim depends from claim 25 (which recites the full length of SEQ ID NO: 46759).

Amended claim 25 recites in part the nucleic acid of claim 21, wherein the sequence of the nucleic acid consists of at least 18 consecutive nucleotides of SEQ ID NO: 46759. Applicant respectfully submits that a nucleic acid of at least 18 consecutive nucleotides of SEQ ID NO: 46759 can also consist of 18 to 120 nucleotides. The nucleic acids of dependent claim 28 can have a maximum length of 24 nucleotides. These nucleic acids, however, fall within the scope of the “at least 18 consecutive nucleotides of SEQ ID NO: 46759” in claim 21. Accordingly, claim 28 does not go beyond the scope of claim 21.

Applicant respectfully submits that dependent claims 27, 36, and 38 are directed to the same limitations as amended claim 25. As discussed above, claims 26, 28, 30, and 40 are

canceled without prejudice. In view of the foregoing amendments and remarks, Applicant respectfully submits that the rejection of claims 25-28, 30, 36, 38, and 40 under 35 U.S.C. § 112, second paragraph has been overcome and should be withdrawn.

**b. Rejection Pursuant to 35 U.S.C. § 112, First Paragraph**

***Claims 21-40***

On pages 9 and 10 of the Office Action, the Examiner rejects claims 21-40 under 35 U.S.C. § 112, first paragraph, asserting that limitation (a) of claim 21, which recites at least 18 consecutive nucleotides of SEQ ID NO: 46759, is not supported by the specification. The Examiner alleges that although paragraph 14 refers to RNAs 18-24 nucleotides in length and although this shorter RNA is disclosed as being produced from the 50-120 nucleotide, the specification does not provide support for precursor RNAs shorter than 50 nucleotides in length. The Examiner further rejects claim 24 for the same reason.

On page 10 of the Office Action, the Examiner further alleges that limitation (c) of claim 21 (which also appears in claim 25), “does not provide support for sequences defined by limitation (a), which can be short as 18 nucleotides...” Thus, the Examiner appears to be offering further grounds for rejecting claim 21 on the allegation that the ratio “34/58” of limitation (c) does not provide support for sequences 18 to 24 nucleotides in length.

Applicant submits that an adequate written description of the invention may be shown by any description of sufficient, relevant, identifying characteristics so long as person skilled in the art would recognize that the inventor had possession of the claimed invention. *See* M.P.E.P. 2163.II.A.3.

On page 10 of the Office Action, the Examiner acknowledges that paragraphs 42969-70 disclose that VGR3152 (which has SEQ ID NO: 46759) encodes a precursor RNA. Applicant respectfully points to following disclosures in the application as originally filed:

1. Paragraph 42971, discloses “that VGR3152 folded precursor RNA, herein designated VGR FOLDED PRECURSOR RNA, comprises a plurality of what is known in the art as hairpin structures.”
2. Paragraph 42972 discloses that “VGR3152 folded precursor RNA, is naturally processed by cellular enzymatic activity into at least seven separate VGAM precursor RNAs...”

3. Paragraph 42972 further discloses that VGAM1930 (SEQ ID NO: 1916) and VGAM1931 (SEQ ID NO: 1917) are two of these seven VGAM precursor RNAs.
4. Paragraph 42973 discloses that the “above mentioned VGAM precursor RNAs are diced [cut] by DICER COMPLEX of Fig. 8, yielding respective short RNA segments of about 22 nucleotides in length...”
5. The short RNA segments discussed in paragraph 42973 (i.e., short DNA segments of about 22 nucleotides in length) are also described in paragraph 0014, which provides a range of lengths for the short RNAs that are produced by RNA precursors (i.e., 18-24 nucleotides in length).
6. Specifically, as acknowledged by the Examiner, paragraph 0014 more specifically discloses that “... RNA encoded by the bioinformatically detectable novel viral gene is about 18 to about 24 nucleotides in length, and originates from an RNA precursor...”

The specification thus discloses that VGR3152 is processed into VGAM1930 and VGAM1931, that these VGAMs are further processed by the Dicer complex into short RNAs of about 22 nucleotides in length, and that these short RNAs may more specifically be about 18-24 nucleotides in length. The totality of these teachings, along with paragraph 0018, establish that the claimed nucleic acids can be 18-24 nucleotides in length.

In view of the foregoing, Applicant respectfully submits that one of ordinary skill in the art would clearly recognize that at the time of filing, the inventor was in possession of subject matter including a folded precursor RNA, at least seven precursor RNAs encoded by the folded precursor RNA, and RNAs of 18 to 24 nucleotides encoded by the precursor RNAs. Accordingly, Applicant submits that the inventor was in possession of the claimed subject matter of claim 21 and respectfully requests that the Examiner reconsider and withdraw the rejection of claim 21.

With regard to the ratio of “34/58,” Applicant is unsure whether the Examiner has clearly outlined a rejection of claims 21 and 24 based on the “34/58” limitation. If so, Applicant respectfully submits that paragraph 42972 and Table 1, lines 13408-13412 of the application as originally filed teach a hairpin represented by SEQ ID NO: 1916 which is 58 nucleotides in length and within which 34 complementary nucleotides are paired. One of ordinary skill in the art would clearly recognize that this degree of complementarity can be described as the ratio

“34/58.” Alternatively, as disclosed by the Examiner in the Office Action, this degree of complementarity can be expressed as a percentage. The percentage 58.7% is equivalent to the ratio “34/58” expressed in percent rounded to the nearest tenth. Nevertheless, in order to expedite prosecution of the instant application, limitation (c) of claims 21 and 25 is amended to recite in part a sequence at least 58.7% identical to (a) or (b).

Applicant respectfully submits that claims 23-25, 27, 28, and 35-38 include the same limitations as claim 21 and therefore also have adequate written description in the application as originally filed. Claims 22, 26, 29-34, 39, and 40 are canceled without prejudice. In view of the foregoing amendment and remarks, Applicant respectfully submits that the rejection of claims 22-40 under 35 U.S.C. § 112, first paragraph, has been overcome and should be withdrawn.

***Claims 39-40***

On pages 8 and 9 of the Office Action the Examiner rejects claims 39 and 40 under 35 U.S.C. § 112, first paragraph. Specifically, the Examiner alleges that the specification does not disclose any specific structures to define the means for inserting the vector into a cell.

Solely to expedite prosecution, and without prejudice to seeking broader claims in a continuing prosecution, claims 39 and 40 are canceled without prejudice. In view of the foregoing amendment, Applicant respectfully submits that the rejection of claims 39 and 40 under 35 U.S.C. § 112, second paragraph, is moot.

**c. Rejection Pursuant to 35 U.S.C. § 102(b)**

***Claims 21, 24, and 37***

On page 11 of the Office Action, the Examiner rejects claims 21, 24 and 37 under 35 U.S.C. § 102(b) as allegedly being anticipated by Dean et al, U.S. Patent No. 6,136,603 (“Dean”). Specifically, the Examiner alleges that Dean teaches a nucleic acid of 20 nucleotides wherein 16 of these nucleotides are complementary to nucleotides 582-597 of SEQ ID NO: 46759.

In view of the foregoing amendment to claims 21, Applicant respectfully submits that claims 21, 24 and 37 are novel over Dean. Specifically, limitation (a) in amended claim 21 recites a nucleic acid of at least 18 consecutive nucleotides of SEQ ID NO: 46759. Amended claim 21 also recites that the at least 18 consecutive nucleotides of (a) is of a sequence selected from the group consisting of SEQ ID NOs: 1916 and 1917. Nucleotides 1-58 of SEQ ID NO: 46759 is the nucleotide sequence of SEQ ID NO: 1916. Nucleotides 684-759 of SEQ ID



NO: 46759 is the nucleotide sequence of SEQ ID NO: 1917. Dean neither teaches nor suggests an 18 consecutive nucleotide sequence over nucleotides 1-58 or 684-759 of SEQ ID NO: 46759.

Accordingly, Dean does not anticipate amended claim 21. Dependent claims 24 and 37 are drawn to the same limitations as claim 21 and are therefore also novel over Dean. In view of the foregoing amendment and remarks, Applicant respectfully submits that the rejection of claims 21, 24, and 37 under 35 U.S.C. § 102(b) has been overcome and should be withdrawn.

**d. Rejection Pursuant to 35 U.S.C. § 102(e)**

***Claims 21, 35, 37, and 39***

On page 12 of the Office Action, the Examiner rejects claims 21, 35, 37, and 39 under 35 U.S.C. § 102(e) as allegedly being anticipated by Homburger et al, U.S. Patent No. 6,703,491 (“Homburger”). Specifically, the Examiner alleges that Homburger teaches a nucleic acid of 61 nucleotides that shares 18 consecutive nucleotides with nucleotides 540-557 of SEQ ID NO: 46759.

In view of the foregoing amendment to claim 21, Applicant respectfully submits that claims 21, 35, 37, and 39 are novel over Homburger. As described above, nucleotides 1-58 of SEQ ID NO: 46759 is the nucleotide sequence of SEQ ID NO: 1916. Nucleotides 684-759 of SEQ ID NO: 46759 is the nucleotide sequence of SEQ ID NO: 1917. Homburger neither teaches nor suggests an 18 consecutive nucleotide sequence over nucleotides 1-58 or 684-759 of SEQ ID NO: 46759.

Accordingly, Homburger does not anticipate amended claim 21. Claims 35 and 37 are drawn to the same limitations as claim 21 and are therefore also novel over Homburger. Claim 39 is canceled without prejudice. In view of the foregoing amendment and remarks, Applicant respectfully submits that the rejection of claims 21, 35, 37, and 39 under 35 U.S.C. § 102(e) has been overcome and should be withdrawn.

***Claims 21 and 37***

On page 13 of the Office Action, the Examiner rejects claims 21 and 37 under 35 U.S.C. § 102(e) as allegedly being anticipated by Okamoto et al, U.S. Patent No. 6,849,431 (“Okamoto”), which allegedly discloses a nucleic acid of 41 nucleotides that shares 18 consecutive nucleotides with nucleotides 536-553 of SEQ ID NO: 46759.

In view of the foregoing amendment to claim 21, Applicant respectfully submits that claims 21 and 37 are novel over Okamoto. As described above, nucleotides 1-58 of SEQ ID

NO: 46759 is the nucleotide sequence of SEQ ID NO: 1916. Nucleotides 684-759 of SEQ ID NO: 46759 is the nucleotide sequence of SEQ ID NO: 1917. Okamoto neither teaches nor suggests an 18 consecutive nucleotide sequence over nucleotides 1-58 or 684-759 of SEQ ID NO: 46759.

Accordingly, Okamoto does not anticipate amended claim 21. Claim 37 is drawn to the same limitations as claim 21 and is therefore also novel over Okamoto. In view of the foregoing amendment and remarks, Applicant respectfully submits that the rejection of claims 21 and 37 under 35 U.S.C. § 102(e) has been overcome and should be withdrawn.

**e. Rejection Pursuant to 35 U.S.C. § 103(a)**

***Claims 21, 24, 35, 37, and 39***

On page 14 of the Office Action, the Examiner rejects claims 21, 24, 35, 37, and 39 under 35 U.S.C. § 103(a) as allegedly being obvious over Dean in view of Noonberg et al, U.S. Patent No. 5,624,803 ("Noonberg"). In view of the foregoing amendments, Applicant respectfully submits that claims 21, 24, 35, and 37 are inventive over Dean alone or in view of Noonberg. Specifically, in order to establish obviousness, the prior art references must teach or suggest all the claim limitations. *See* M.P.E.P. 2143.

As described above, Dean does not teach or suggest the nucleic acid of amended claim 21. Rather, Dean teaches a 20 nucleotide-long nucleic acid that shares 17 bases of complementarity with nucleotides 582-597 of SEQ ID NO: 46759. Dean fails to teach or suggest at least 18 consecutive nucleotides of SEQ ID NO: 46759, wherein the at least consecutive nucleotides are of a sequence selected from the group consisting of SEQ ID NOs: 1916 and 1917.

Noonberg does nothing to correct the deficiency of Dean. Noonberg does not teach or suggest any sequence related to a nucleic acid with the nucleotide sequence as set forth in SEQ ID NO: 46759. Rather Noonberg only teaches a means for inserting vectors via liposomes or localized injection. Dependent claims 25, 35, and 37 are drawn to the same limitations as claim 21. As stated above, solely to expedite prosecution and without prejudice to seeking similar claims in a continuing application, Applicant has canceled claim 39 without prejudice.

In conclusion, Applicant submits that Dean either alone or in combination with Noonberg neither teaches nor suggests Applicant's claimed subject matter of claim 21. Similarly, claims 24, 35, and 37 are drawn to the same limitations as claim 21 and are not obvious in over Dean in

view of Noonberg. Accordingly, without such teaching or suggestion, the Examiner can not established a *prima facie* case of obviousness for the amended claims. Claim 39 is canceled without prejudice. In view of the foregoing remarks and amendments, Applicant respectfully submits that the rejection of claims 21, 24, 35, 37, and 39 under 35 U.S.C. § 103(a) has been overcome and should be withdrawn.

### 3. Conclusion

Applicant respectfully submits that the instant application is in good and proper order for allowance and early notification to this effect is solicited. If, in the opinion of the Examiner, a telephone conference would expedite prosecution of the instant application, the Examiner is encouraged to call the undersigned at the number listed below.

Respectfully submitted,

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Dated: April 16, 2007

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